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Anh Nguyen
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To: NCIC HPV@EPA
cc:
Subject: Environmental Defense comments on Benzyltrimethylammonium Chloride (CAS# 56-93-9)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 04/05/2004 08:09 AM -----

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04/04/2004 07:48 PM

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Subject: Environmental Defense comments on Benzyltrimethylammonium Chloride (CAS# 56-93-9)

(Submitted via Internet 4/4/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Cynthia.graham@bayerpolymers.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Benzyltrimethylammonium Chloride (CAS# 56-93-9).

The test plan and robust summaries for benzyltrimethylammonium chloride (BTMAC) were submitted by Bayer Chemicals. According to the test plan BTMAC is used as a solvent for cellulose, a gelling inhibitor for polyester resins, an undefined intermediate, a dye assistant for acrylics and a phase transfer agent. No information was provided on actual or potential environmental releases, although, based on its uses, it must be assumed that some amount of this chemical is released into the environment. Also, no information was provided on worker or consumer exposures, but again given its apparent uses it is likely that human exposures occur.

The sponsor states that existing data are adequate to fulfill requirements for the HPV program, with the exception that a developmental toxicity study is proposed because there are no available data on this SIDS endpoint. While we agree that a developmental toxicity study is needed, we recommend that a combined reproductive/developmental toxicity study be conducted and also that an acute fish toxicity study be conducted. Specific comments are as follows.

1. Biodegradation studies indicate that BTMAC is essentially not biodegradable: less than 1% degradation over 28 days. The sponsor contends that this does pose a problem for bioaccumulation because acclimation profoundly influences the biodegradability and hence this compound should not be considered persistent. No data are provided to substantiate this claim, so we cannot accept the sponsor's conclusion at this time. In addition, if it is degraded, what are the degradation products and what is known about their persistence and toxicity?

2. The sponsor indicates that ECOSAR studies predict that fish toxicity is low, yet the data presented in the robust summaries do not support this claim. It appears ECOSAR predicts that fish are nearly as susceptible as aquatic invertebrates to BTMAC. No toxicokinetic information is provided to indicate that fish would be resistant to the toxic effects of BTMAC. Because of these concerns coupled with the knowledge that BTMAC is highly

toxic to rodents and it appears not be biodegradable, we recommend that the sponsor conduct an acute fish toxicity study on BTMAC.

3. Genetic toxicity and repeat dose studies are adequate to fulfill HPV requirements. The genetic studies indicate that BTMAC likely possesses some genetic toxicity potential based on chromosomal aberration and micronucleus studies. The repeat dose studies are well done, were conducted in multiple species and indicate that BTMAC exhibits considerable neurological toxicity at doses as low as 25 mg/kg as evidenced by an array of cholinergic effects.

4. The sponsor proposes to conduct a developmental toxicity study since none are available. In addition the sponsor proposes to use analyses from the repeat dose study to fulfill requirements of the reproductive toxicity endpoint. We disagree with this proposal because BTMAC apparently disrupts diestrus, it exhibits high acute toxicity and it is a neurotoxin at low doses. All of these findings indicate a clear potential for reproductive toxicity. Accordingly, we recommend that the sponsor conduct combined reproductive/developmental toxicity study on BTMAC.

Thank you for this opportunity to comment.

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